REMARKS

Claims 16-19 were previously presented for examination. In the current Office Action, the Examiner has rejected the claims on the following grounds:

1. Under 35 U.S.C. §112, first paragraph, as lacking enabling disclosure (claim 19); and

2. Under 35 U.S.C. §102(b), as anticipated by Bombeli et al (claims 16-18).

Additionally, the Examiner has maintained her objection to the misspelling of "neurological" in claim 19.

It is respectfully requested that the above amendment be entered pursuant to the provisions of 37 C.F.R. §1.116(b); that this application be reconsidered in view of the above amendment and the following remarks; and that all of the claims remaining in this application be allowed. With the above amendments, Claim 19 has been amended and new Claims 47-52 have been added. Thus, Claims 16-19 and 47-52 are now pending.

As required by 37 CRF §1.121, amendments made to claim 19 are shown in attached Appendix A, entitled " REDACTED CLAIMS INDICATING AMENDMENTS MADE" and for the Examiner's convenience the currently pending claims, as amended herein, are presented in Appendix B.

The rejections are addressed, in-part, by the above amendments and, in-part, by the arguments that follow.

THE AMENDMENTS AND NEW CLAIMS:

Claim 19 has been amended to remove objected-to language.

New Claims 47-52 have been added. The new claims parallel originally filed Claims 3, 6-7, 13, and 14.

Accordingly, no new matter has been added and entry of the amendments is in order.

Applicants submit that these amendments places the claim in better condition for allowance or, alternatively, simplifies issues for Appeal and, accordingly, entry of the

amendments is therefore proper under 37 C.F.R. §1.116(b). Therefore, entry of this amendment is earnestly solicited. Applicants reserve the right to pursue the canceled subject matter in a continuation or divisional case.

WITHDRAWN REJECTIONS:

Applicants note with appreciation the withdrawal of the previously raised rejection under 35 U.S.C. §112, first paragraph, of claims 17 and 18 and of the rejection under 35 U.S.C. §102(b) over Fadok et al.

THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH:

Claim 19 stands rejected under 35 U.S.C. §112, first paragraph. While not acquiescing in this rejection and solely in the interest of expediting prosecution, Applicants have deleted the objected to language from Claim 19.

It is noted that a parallel amendment to claim 17 in the previous response, paper 11, was deemed by the Examiner as sufficient to overcome a 35 U.S.C. §112, first paragraph, rejection. As before, the amendment of claim 19 is without prejudice to the filing of a continuation application directed to this subject matter.

As the rejection is now moot, reconsideration and withdrawal of the rejection are in order and are respectfully requested.

THE REJECTION UNDER 35 U.S.C. §102(B) AS ANTICIPATED BY BOMBELI ET AL.:

Claims 16-18 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Bombeli et al. (hereinafter "Bombeli"). The Examiner has cited the reference as teaching apoptotic human umbilical vein endothelial (HUVEC) cells stored in a culture medium. While the Examiner acknowledges that Bombeli does not specifically disclose the concentration of the apoptotic HUVEC cells contained in the culture medium, she states that one skilled in the would reasonably conclude that the concentration of the cells within the medium fell within the 10% to 90% range specified in rejected claims and that the reference, therefore, anticipated the rejected claims. Applicants disagree.

As the Examiner is aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "Rejections under 35 U.S.C. §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art...." *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Air Products and Chemicals, Inc. v. Chas. Tanner Co.*, 219 USPQ 223, 231 (D.S.C. 1983); *Imperial Chemical Industries v. Henkel Corp.*, 215 USPQ 314, 323 (D. Del. 1982); *In re Samour*, 197 USPQ 1 (CCPA 1978). In the present instance, the cited reference clearly fails to expressly or inherently describe every element as set forth in the rejected claims.

Independent claim 16 recites a pharmaceutical composition comprised of a pharmaceutically acceptable excipient and an effective amount of human apoptotic bodies and/or apoptotic cells. In contrast, Bombeli discloses human apoptotic cells that are stored in RPMI 1640 growth medium. Applicants submit that this disclosure in no way encompasses the pharmaceutical composition of the claims. While the growth medium disclosed in Bombeli could be classified as the biologically acceptable liquid suspending medium discussed on page 11, lines 12 to 15, of the specification, such a growth medium cannot be classified as a pharmaceutically acceptable excipient. Clearly, independent Claim 16 is not anticipated by the cited reference.

Furthermore, as Bombeli is completely focused on an exploration of the procoagulent behavior of apoptotic cells and not on treatment methods using such cells, there would be no motivation for one of ordinary skill in the art to modify the stored cells of Bombeli by the addition of a pharmaceutically acceptable excipient to arrive at the pharmaceutical composition of the presently pending claims. Independent Claim 16 is not anticipated by the teaching of the reference, nor is any claim dependent thereupon, i.e., Claims 17 and 18.

Therefore, as Bombeli fails to disclose each and every element of the presently pending claims, the reference does not provide a basis for *prima facie* anticipation. The rejection is in error and its reconsideration and withdrawal are respectfully requested.

CONCLUSION

Accordingly, for the reasons set forth above, it is submitted that entry of this Amendment will place the application in condition for allowance and such entry and allowance are requested. Alternately, entry of this Amendment is requested as placing the application in better condition for appeal. A Notice of Appeal is being submitted herewith to prevent inadvertent abandonment of the application.

If the Examiner has any questions concerning this communication, please contact the undersigned at (650) 622-2300.

Respectfully submitted,

Date: 4-30-03

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APPENDIX A

REDACTED CLAIMS INDICATING AMENDMENTS MADE

IN THE CLAIMS:

Please amend Claim 19 and add new Claims 47-52 as indicated below. Text to be deleted is indicated as ~~deleted text~~, while added text is underlined.

19. (Amended) A unit dosage composition for administration to a human patient ~~for alleviation or prophylaxis of a nuerological or neurodegenerative disorder~~, comprising a liquid suspension of cellular material including from about 10,00 to 10,000,000 apoptotic cells and/or apoptotic bodies per kilogram of patient body weight.

APPENDIX B

PENDING CLAIMS AFTER AMENDMENT HEREIN

16. A pharmaceutical composition comprising a pharmaceutically acceptable excipient and an effective amount of human apoptotic bodies and/or apoptotic cells.

17. The pharmaceutical composition of claim 16 wherein said apoptotic cells and/or bodies comprise no more than 35 weight percent necrotic cells and/or bodies.

18. The composition of Claim 16 or 17 comprising a liquid suspension of cellular material, form 10% to 90% of the cellular material being apoptotic bodies and/or apoptotic cells.

19. A unit dosage composition for administration to a human patient, comprising a liquid suspension of cellular material including from about 10,000 to 10,000,000 apoptotic cells and/or apoptotic bodies per kilogram of patient body weight.

47. The unit dosage composition of Claim 19, wherein the dosage contains from about 500,000 to about 5,000,000 apoptotic bodies and/or apoptotic cells per kilogram of body weight of said patent.

48. The unit dosage composition of Claim 47, wherein the dosage contains from about 1,500,000 to about 4,000,000 apoptotic bodies and/or apoptotic cells per kilogram of body weight of said patent.

49. The composition of Claim 16, wherein the apoptotic bodies and/or apoptotic cells are in a liquid suspension along with viable cells.

50. The composition of claim 16, wherein the apoptotic bodies and/or apoptotic cells are derived from extracorporeal treatment of human blood cells.

51. The composition of Claim 50, wherein the apoptotic bodies and/or apoptotic cells are derived from established cultured cell lines.

52. The composition of Claim 50, wherein the human blood cells are white blood cells.